PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Keith R. D'ALESSIO et al.

Application No.: 09/430,289

Filed: October 29, 1999

Group Art Unit: 1772

Examiner: S. HON

Docket No.: 100497.02

#20

For: POLYMERIC CONTAINERS FOR 1,1-DISUBSTITUTED MONOMER COMPOSITIONS

DECLARATION UNDER 37 C.F.R. §1.132

Director of the U.S. Patent and Trademark Office
Washington, D.C. 20231

Sir:

I, Keith R. D'Alessio, a citizen of the United States, hereby declare and state:

1. I have a Bachelor of Science degree in Materials Engineering, which was conferred upon me by Drexel University in Philadelphia, Pennsylvania in 1986, and a Master's degree in Mechanical Engineering, which was conferred upon me by the University of Bridgeport in Bridgeport, Connecticut in 1990.

2. I have been employed by Closure Medical Corporation since 1997 and I have had a total of 16 years of work and research experience in plastics and medical devices.

3. I am a member of Alpha Sigma Mu, Pi Tau Sigma, the Society of Biomaterials, and ASTM International.

4. I have reviewed and am familiar with the disclosure and claims of the above-identified patent application, and the references cited in the Final Rejection mailed January 24, 2002.

5. In the January 24, 2002, Final Rejection, the Patent Office cites Colvin, U.S. Patent No. 3,523,628. The Patent Office argues that Colvin teaches fluorinated containers, which containers correspond to the containers and combinations of the presently claimed invention. The Patent Office further argues, in response to Applicants' arguments that the claimed containers and combinations are in fact different, that Applicants have not provided any evidence demonstrating that difference.

In response, I affirm that the containers and combinations of the presently claimed invention, comprising a polymeric resin matrix including at least one post-halogenated polymeric material, are different from the containers of Colvin. In particular, the post-halogenated polymeric materials of the presently claimed invention are different from, and exhibit different properties from, the pre-fluorinated polymeric materials described in Colvin.

6. By way of explanation only, attached hereto as Fig. 1 is a graphical representation of two polymeric materials. The first (Fig. 1a) is a polymeric material that is post-halogenated (e.g., post-fluorinated) according to the present invention. The second (Fig. 1b) is a polymeric material that is pre-halogenated (e.g., formed from a fluoropolymer), similar to that used in Colvin. As shown in Fig. 1a, a post-fluorinated polymeric material generally only has fluorine species located on or near the surface of the polymer material. The fluorine species do not permeate and fluorinate the entire polymeric material, but rather are localized only on the surface thereof. In contrast, a pre-fluorinated polymeric material generally includes fluorine species located substantially homogeneously throughout the bulk material. The fluorine species are initially part of the polymer used to form the material, and thus remain distributed throughout the bulk material.

Although Fig. 1 is graphical in nature only, it demonstrates a major difference between post-halogenated and pre-halogenated materials.

7. To further demonstrate that the different polymeric materials used to form containers provide different functional properties, I and/or those under my direct supervision and control have conducted the following experiments:

A. Moisture Vapor Transmission Rate

Ten otherwise identical 3 mL high density polyethylene bottles were selected. Five of the bottles were subjected to a post-fluorination treatment according to the claimed invention, while the other five bottles were not treated. Each of the bottles was tested to determine the moisture vapor transmission rate (MVTR) at conditions of 40°C and 75% relative humidity. The testing was conducted by filling the respective bottles with dessicant; placing the filled bottles in a heated testing chamber; and measuring a weight gain of the filled bottles over time, which weight gain corresponded to the moisture uptake of the dessicant in the bottles.

The results of the MVTR testing is set forth in Table I:

Table I

Specimen type	Average MVTR	Standard Deviation	Number specimens
Virgin HDPE	2.08×10^{-5} g/hr	0.14×10^{-5} g/hr	N=5
Post-fluorinated HDPE	2.03×10^{-5} g/hr	0.07×10^{-5} g/hr	N=5

The results in Table I indicate that the post-fluorinated HDPE bottles actually have substantially the same MVTR as virgin, i.e., non post-fluorinated, HDPE bottles. In contrast, Colvin teaches that virgin HDPE containers exhibit moisture vapor transmission rates that are significantly higher that moisture vapor transmission rates for the disclosed containers formed from pre-fluorinated materials. See Colvin at col. 1, lines 57-64 and col. 2, lines 32-44.

B. Surface Energy

Six containers made from various polymer materials were obtained and tested to determine the surface energy of the respective containers. In particular, the containers included

one non-fluorinated container, two different post-fluorinated containers, and three different pre-fluorinated containers. The post-fluorinated containers correspond to the containers of the present invention, while the pre-fluorinated containers generally correspond to the fluorinated resin materials disclosed for use in Colvin. The testing was conducted as follows:

Surface energy testing was conducted using ACCU DYNE TEST™ Marker Pens, available from Diversified Enterprises, Clairmont, NH. These pens contain solutions that conform to ASTM D-2578, Standard Test Method for Wetting Tension of Polyethylene and Polypropylene Films. Each of the container materials is wetted with solution from the various pens to determine the surface energy of the polymeric material being tested.

The results of the surface energy testing is set forth in Table II:

Table II

SAMPLE TYPE	SURFACE ENERGY (dyne/cm)
Non-fluorinated HDPE	46
Post-fluorinated HDPE	58 to >60
Post-fluorinated HDPE	>60
Pre-fluorinated PFA	<30
Pre-fluorinated FEP	<30
Pre-fluorinated ETFE	<30

NOTE: HDPE = high density polyethylene; PFA = perfluoroalkoxy resin; FEP = fluorinated ethylene propylene; ETFE = ethylene-tetrafluoroethylene copolymer

The results in Table II indicate that the post-fluorinated HDPE bottles actually have increased surface energy, as compared both to virgin (non-fluorinated) HDPE bottles and bottles formed from pre-fluorinated materials. In contrast, Colvin teaches that fluorinated resins have a surface energy lower than non-fluorinated resins, and that surface energy values of 35 dyne/cm or less are required for storage of cyanoacrylate. See Colvin at col. 4, lines 16-20.

8. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so

made are punishable by fine and/or imprisonment under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefore.

Date: 6/21/02 Keith R. D'Alessio

Keith R. D'Alessio

Attachment:
Figs. 1a-1b

FIG. 1a:

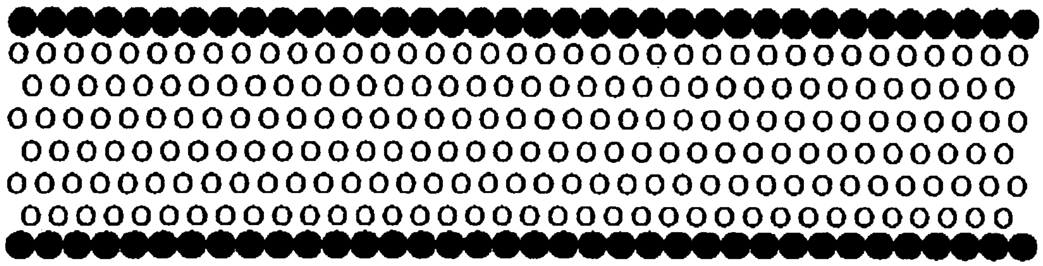
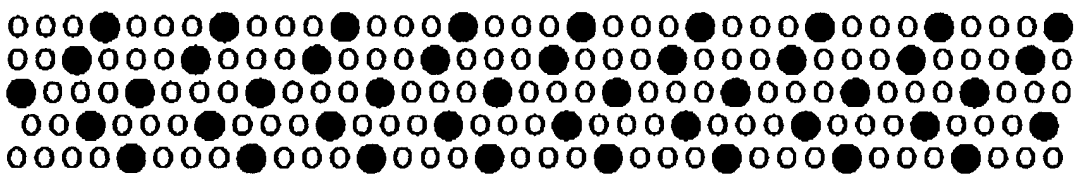


FIG. 1b:



KEY:

O = Polymer matrix material

● = Fluorine atoms